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NOTIFICATION OF ELECTION	Assistant Commissioner for Patents United States Patent and Trademark
(PCT Rule 61.2)	Office Box PCT Washington, D.C.20231 ÉTATS-UNIS D'AMÉRIQUE
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nternational filing date (day/month/year) 22 July 1999 (22.07.99)	Priority date (day/month/year) 22 July 1998 (22.07.98)
Applicant CANHAM, Leigh, Trevor et al	
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The International Bureau of WIPO	Authorized officer S. Mafla
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

International application No. PCT/GB99/02381 22/07/1999 22/07/1999 22/07/1998 Priority date (day/monthrysar) PCT/GB99/02381 22/07/1999 22/07/1998 Priority date (day/monthrysar) 22/07/1998 International Patent Classification (IPC) or national classification and IPC B81B1/00 Applicant THE SECRETARY OF STATE FOR DEFENCE et al. 1. This international preliminary examination report has been prepared by this International Preliminary Examining At and is transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 7 sheets, including this cover sheet. Solution This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which has been amended and are the basis for this report and/or sheets containing rectifications made before this Author (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of 5 sheets. 3. This report contains indications relating to the following items: Solution Solution Solution Solution Supporting such statement Non-establishment of opinion with regard to novelty, inventive step and industrial applicability clations and explanations suporting such statement Non-establishment of opinion with regard to novelty, inventive step or industrial applicability clations and explanations suporting such statement Non-establishment of opinion with regard to novelty, inventive step or industrial applicability clations and explanations suporting such statement Certain documents cited VII Certain defects in the international application	Applicant's or	agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
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IV			opinion with regard to novelty, in	ventive step and industrial applicability
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preliminary examining authority: European Patent Office	15/02/200	00	17.10	2000
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1. This report has been drawn on the basis of (substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.):

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	Desc	cription, pages:				
	1-39		as originally filed			
	Claiı	ns, No.:				
	1-36		as received on	08/08/2000	with letter of	04/08/2000
	Drav	vings, sheets:				
	1/9-	9/9	as originally filed			
2.	The	amendments hav	e resulted in the cancellation of	:		
		the description,	pages:			
		the claims,	Nos.:			
		the drawings,	sheets:			
3.		This report has be considered to go	een established as if (some of) beyond the disclosure as filed (the amendme (Rule 70.2(c)):	nts had not been mad	e, since they have been
4.	Add	litional observation	ns, if necessary:			

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 1,8

No: Claims 36

Inventive step (IS) Yes: Claims 17

No: Claims 1,8

Industrial applicability (IA) Yes: Claims 1-36

No: Claims

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

INTERNATIONAL PRELIMINARY **EXAMINATION REPORT - SEPARATE SHEET**

Section V

Reference is made to the following document/s/: 1.

D1: US5137817

D2: US5383512

D3: US5262128

D4: US96/07395

D5: US5457041

D6: WO97/04297

- The present application does not satisfy the criterion set forth in Art. 33(2) PCT 2. because the subject-matter of claim 36 is not new in respect of prior art as defined in the regulations (Rule 64(1)-(3)).
- 2.1 Product claim 36 is defined in terms of a "product by process" feature cf. "fabricated according to the methods of any one of claim 1 to 35". Such a formulation is only allowable if the product arising from any of these methods is distinguishable from the micro-needle of the prior art.

In the present case, there are three methods, cf. claims 1,8 & 17 of making the micro-needle which are quite distinct, by inspection; the methods of claims 1 & 8 provide a ducted needle of silicon material, being the same as the substrate material whilst the method of claim 17 is directed to providing a ducted needle of different material to that of the substrate, viz. any material i.e. the needle material of claim 36 is not specified. Moreover, the processes of manufacture involving removal of surrounding substrate or needle material deposition are such that an unambiguous structural feature of the end product is not evident. Accordingly, the distinguishable feature of the device of claim 36 is "A micro needle".

This subject-matter is, however, not novel for the following reasons:

D1, cf. Figs. 4C,4F & corresponding Text discloses a micro-tube (20,37) fabricated onto the surface of a first material (12).

Further documents D2, cf. Figs. 2A-2C & corresponding Text, D3, cf. Fig.4 & corresponding Text & col.2 lines 17-53, D4, cf. Fig.1 & corresponding Text, D5, cf. Figs.4A,4B & corresponding Text & D6, cf. Figs.2B,2C & corresponding text also take away the novelty of the claimed subject-matter, by inspection.

Having regard to the nature of the above objection, it does not appear that an allowable device claim can be formulated.

- 3. The present application does not satisfy the criterion set forth in Art. 33(3) PCT because the subject-matter of claims 8 & 1 does not involve an inventive step in respect of prior art as defined in the regulations (Rule 64(1)-(3)).
- 3.1 Regarding claim 8, attention is drawn to the claimed feature "a duct in <u>at least a region of said tip</u>", i.e. not necessarily extending through the entire needle tip, which is also supported by the description, cf. Fig.16 & associated text. The subject-matter of this claim is not inventive with regard to D5, for the following reason:

D5, cf. Fig.5 & corresponding text inc. col.8 line 52 to col.10 line 15, discloses a method of providing a silicon micro-needle (12), the micro-needle having a base adjoining a silicon substrate (16), a tip (28) remote from said base and a duct in at least a region of said tip (inc. col.7 line 58 "hollow or concave" i.e. a duct region), the method comprising:

- a. selectively removing the silicon substrate to provide a micro needle (cf. col.8 line 59 to col.9 line 55)
- b. providing a duct coincident with the micro-needle.

Accordingly, the claimed matter differs from that of D5 in that step (b) is subsequent to step (a). The skilled person, on reading the col.8 text immediately realises that the needle tip region is covered with the silicon dioxide pattern, which clearly must be removed, subsequent to any hollow formation (this being done by etching). Since a two step nature of the D5 process immediately follows, an inventive nature is not appreciated.

INTERNATIONAL PRELIMINARY **EXAMINATION REPORT - SEPARATE SHEET**

- 3.2 For completeness, a futher objection of lack of inventive step of claim 8 is made having regard to D3, cf. Fig.4 & corresponding text, particularily col.6 lines 55-57. In this regard, it is apparent to the skilled person from the text of D3 (cf. col.4 line 56 to col.5 line 13) & knowing that "micromachining a silicon chip utilising techniques well known in the integrated circuit industry", will thus actively seek such techniques to fabricate microneedles (their angle to the substrate not being specified in the claim) i.e. adapt the "Liga" process accordingly, knowing that this process is suited to a wide variety of materials and, in particular, that lithography & etch of semiconductors (also being metallic when doped) & metals is equally possible.
- 3.3 Having regard to claim 1, it is apparent to the skilled person that the method disclosed in D3, Fig.4 & corresponding text, cf. col.4 line 56 to col.5 line 13 as well as col.6 lines 55-58 also provides a silicon micro needle comprising providing a ducted silicon substrate, cf. also the references to the "liga" process of Section 3.2, an inventive nature of this subject-matter being not determined.
- The present claims 1,8 & 36 are not allowable for these reasons. 4.

Section VII

The documents D1-D6 have not been identified in the description nor has the relevant prior art disclosed therein been discussed. The requirements of Rule 5.1(a)(i) PCT are therefore not fulfilled.

The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Section VIII

Having regard to a patentable nature of the subject-matter of the application, it 1. appears that a claim 17, clarified to render the order of the process steps unambiguous (the present amended form comprises any order) is not known from

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or is obvious with regard to the available search documentation. In particular, closest prior art D1, discloses a two material microneedle fabrication process in which the duct evidently may only be formed after the second material is deposited i.e. the known process is not adaptable to forming a duct as claimed in a clarified claim 17 process.

Having regard to the additional subject-matter of claims 2-7 & 9-16, this matter is known from D1,D2,D3 & D5, cf. above citations and therefore could not be considered new or inventive.

For completeness, the common concept linking the claims 1,8 & 17 viz. providing 2. a microneedle with a duct is known from any of D1,D2,D3 & D5, cf. above citations, giving rise to an objection of lack of unity, R13(1) PCT.

CLAIMS

- 1. A method of providing a micro-projection on the surface of a first material, the micro-projection having a base portion adjacent the first material and a remote, or a tip portion, and a duct at least in a region of the tip portion and the method comprising micro-machining the first material to provide the micro-projection and duct.
- 2. A method according to claim 1 in which the duct passes between the tip portion and the base portion.
 - 3. A method according to claim 1 or 2 in which the duct passes entirely through the micro-projection.
- 15 4. A method according to any preceding claim in which the base portion has a width of less than approximately 1000µm.
 - 5. A method according to any preceding claim in which the duct is fabricated to be coincident with an apex of the micro-projection.

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6. A method according to any preceding claim in which the duct is fabricated in a piece of the first material and subsequently the micro-projection is fabricated in the first material such that the micro-projection is co-incident with the duct.

- 7. A method according to any preceding claim in which a masking layer is formed on to the surface of the first material.
- 8. A method according to claim 7 in which the masking layer 30 comprises silicon dioxide.

- 9. A method according to claims 7 or 8 in which an aperture is formed into the masking layer using lithographic techniques.
- 5 10. A method according to claim 9 in which the first material is removed from a region underneath the aperture in the masking layer to form a duct.
- 11. A method according to any of claims 6 to 10 in which the micro-projection is formed by any of the following techniques:

 a) anisotropic wet etching of silicon using liquid alkaline etches;
 b) focused ion beam milling; or c) transferring a pattern to the first material from a domed region of the masking layer using plasma/ion beam etching.

- 12. A method according to any of claim 7 to 10 in which the masking layer is removed from the first material.
- 13. A method according to claim 12 in which a second masking layer is20 created on the first material after the removal of the first masking layer.
 - 14. A method according to claim 13 in which the second masking layer is silicon dioxide.
- 25 15. A method according to claim 13 or claim 14 in which the first material is etched using an anisotropic etch which undercuts the masking layer.

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- 16. A method according to claim 15 in which the crystal planes of the first material are arranged so that planes having a low etch rate bound the etching process creating the desired micro-projection structure.
- 5 17. A method according to claims 15 or 16 in which the second masking layer is then removed.
 - 18. A method according to claim 13 or claim 14 in which a portion of the second masking layer covering the top surface of the first material is removed so as to leave the second masking layer covering the inside surface of the duct.
 - 19. A method according to claim 18 in which the first material is then removed from around the second masking layer on the inside surface of the duct leaving the masking layer substantially intact.
 - 20. A method according to claim 19 in which the micro-projection is fabricated from a second material which is different from that of the first material.

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- 21. A method according to claim 18 in which a portion of the second masking layer covering of the inside surface of duct is removed before the first material is removed from around the second masking layer.
- 25 22. A method according to any of claims 18 to 21 in which the cross section of the micro-projection is defined by the cross section of the duct.
 - 23. A method according to any of claims 18 to 22 in which the cross section of the duct is circular, square, rectangular, or elliptical.

- 24. A method according to any of claims 18 to 23 in which the second masking layer is SiO_2 , a metal, ceramic, or a polymer or a semiconductor.
- 5 25. A method according to any of claims 1 to 5 in which the method comprises fabricating the micro-projection from the material and subsequently forming the duct through the micro-projection.
- 26. A method according to claim 25 in which, as the first step of the process, a masking layer is created on to the surface of the first material.
 - 27. A method according to claim 26 in which the masking layer is substantially in the shape of a square, or a modified square.
- 15 28. A method according to claim 26 or 27 in which the masking layer is silicon dioxide.
 - 29. A method according to any of claims 25 to 28 in which the first material is etched using an anisotropic etch which undercuts the masking layer.
 - 30. A method according to claim 29 in which the crystal planes of the first material are arranged so that planes having a low etch rate bound the etching process creating the desired micro-projection structure.

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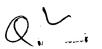
31. A method according to any of claims 25 to 30 in which the duct is fabricated such that the duct is coincident with an apex of the micro-projection.

- 32. A method according to any of claims 25 to 28 in which the micro-projection is formed by one of the following techniques: a) anisotropic wet etching of silicon using liquid alkaline etches; b) focused ion beam milling; or c) transferring the pattern to the silicon from a domed resist mask using some form of plasma/ion beam etching.
- 33. A method according to claims 29 or 30 in which the remaining first material is covered in a planarising layer.
- 10 34. A method according to claim 33 in which the planarising layer is patterned using lithography and etched to reveal a portion of the first material.
- 35. A method according to claim 34 in which the portion of the first material which has been revealed has a maximum cross sectional area, taken normal to its axis, substantially equal to the cross sectional area, taken normal to its axis, of the duct to be formed.
- 36. A method according to claim 38 or 39 in which once the portion of the first material has been revealed the duct is etched.
- 37. A method according to any preceding claim in which once the micro-projection and duct have been created the method further includes25 linking the duct to a reservoir.
 - 38. A method according to claim 37 in which a portion of the first material is removed from a side opposite a side of the first material where the micro-projection has been fabricated.

- 39. A method according to claims 37 or 38 in which the first material is attached to a second piece of material.
- 40. A method according to claim 39 in which the second piece of material has a channel which connects to the duct and links the duct to a reservoir.
 - 41. A method according to claim 39 or claim 40 in which the first material has a channel which connects to the duct and links the duct to a reservoir.
 - 42. A method according to any one of claims 39 to 41 in which the two pieces of material are fabricated from same material.
- 15 43. A method according to any preceding claim in which the surface of the material of the micro-projection is modified.
 - 44. A method according to claim 43 in which the surface of the material of the micro-projection is porosified.
 - 45. A method according to claim 44 in which the porosification is performed by electrochemical anodisation processes or by immersing the structure into a stain etching solution.
- 25 46. A method according to any preceding claim in which the microprojection is fabricated substantially normal to the surface of the first material.

- 47. A method according to any of claims 1 to 46 in which the microprojection is fabricated inclined at an acute angle relative to the surface of the first material.
- 5 48. A method according to any preceding claim in which one of the following etching techniques is used to etch the duct: a) deep dry etching wherein the planarising layer acts as a mask; b) anodisation of the structure; c) laser ablation; or d) focused ion beam milling.
- 10 49. A method according to claim 48 in which anodisation of the structure takes place using an HF containing solution.
 - 50. A micro-projection having a base portion which is provided on the surface of a first material, and a remote, or a tip, portion wherein the micro-projection has a duct at least in a region of the tip portion.
 - 51. A micro-projection according to claim 50 in which the duct passes between the tip portion and the base portion.
- 20 52. A micro-projection according to claim 50 or 51 in which the duct passes entirely through the micro-projection.
 - 53. A micro-projection according to any of claims 50 to 52 which is a micro-needle, a micro-barb or a micro-tube, micro-cuvette, a micro-conduit, micro-connector, micro-rod or the like.
 - 54. A micro-projection according to any of claims 50 to 53 in which the base portion has a width of less than approximately 1000µm.
- 30 55. A micro-tube fabricated onto the surface of a first material.

- 56. A micro-tube according to claim 55 in which the micro-tube has base portion with a width of less than approximately 1000µm.
- 5 57. A micro-tube according to claims 55 or 56 in which the micro-tube is fabricated from a substance other than that of the first material.
- 58. A micro-tube according to claim 55 in which the first material is silicon and the micro-tube is fabricated from one of the following materials: SiO₂, a metal, a ceramic, or a polymer, or a semiconductor, or a plastics material.
 - 59. A micro-tube according to any of claims 55 to 58 in which the micro-tube has substantially one of the following cross sections: square, rectangular, circular, elliptical.
 - 60. A micro-tube according to any of claims 55 to 59 which comprises a micro-cuvette.
- 20 61. A micro analysis system in which a micro tube according to any of claims 55 to 60 is provided and in which an analysis means is provided to analyse a substance within the micro tube.
- 62. A micro analysis system according to claim 61 which comprises
 25 more than one micro tube.
 - 63 A micro analysis system according to claim 60 or 62 which comprises a delivery means allowing chemicals, or other substances to be delivered into the micro tube.



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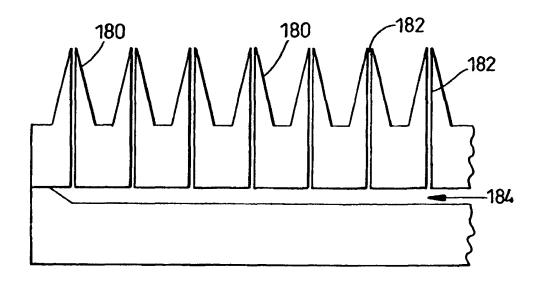
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(54) Title: SILICON MICRO-MACHINED PROJECTION WITH DUCT



(57) Abstract

A method of providing a microprojection (180) on the surface of a first material, the microprojection having a base portion adjacent the first material and a remote, or a tip portion, and a duct (182) at least in a region of the tip portion and the method comprising micro-machining the first material to provide the micro-projection duct. Various uses of the microprojection are also disclosed including light guides and cuvettes from micro-analytical systems, microneedles for transdermal fluid delivery or the like.





ational Application No

PCT/GB 99/02381 CLASSIFICATION OF SUBJECT MATTER PC 7 B81B1/00 B81C ĨPC 7 B81C1/00 G01N21/03 According to International Patent Classification (IPC) or to both national classification and IPC **B. FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) IPC 7 C12M G01N B01L B01J A61M B81B B81C Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the International search (name of data base and, where practical, search terms used) C. DOCUMENTS CONSIDERED TO BE RELEVANT Category ° Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. X WO 97 04297 A (NORTHEASTERN UNIV) 50-56,59 6 February 1997 (1997-02-06) A 61 - 63page 1, line 31 -page 3, line 35 page 10, line 7 -page 11, line 3 figures 1A,1B,2B,2C X US 5 137 817 A (BUSTA HEINZ H ET AL) 50-57,59 11 August 1992 (1992-08-11) column 10, line 39 -column 11, line 14; figures 4C,4F,4G X WO 96 37256 A (SILICON MICRODEVICES INC; 50-56. **GODSHALL NED A)** 58.59 28 November 1996 (1996-11-28) page 5, line 1 -page 6, line 21 claims 1-5; figure 1 -/--X Further documents are listed in the continuation of box C. Patent family members are listed in annex. Special categories of cited documents: "I" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to " document which may throw doubts on priority claim(s) or involve an inventive step when the document is taken alone which is cited to establish the publication date of another citation or other special reason (as specified) document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "O" document referring to an oral disclosure, use, exhibition or document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 2 3. 12. 99 9 November 1999 Name and mailing address of the ISA **Authorized officer** European Patent Office, P.B. 5818 Patentiaan 2 NL - 2280 HV Rijewijk Tel. (+31-70) 340-2040, Tx. 31 651 epo ni,

Fax: (+31-70) 340-3018

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Köpf, C

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 1-49

The term "micro-machining" has no well established meaning in the art: It describes a generic technology which may use a huge number of different techniques or combinations of techniques. Furthermore it is excessively relative due to the prefix "micro". At the other end it obviously appears that a process for fabricating a -micro-projection must use -micro-fabrication techniques, and consequently -micro-machining of materials.

Additionally it is noted that the document US 5 262 128, acknowledged in the application and mentioned as being unsuitable to fabricate the microprojections in question, discloses in col. 6 the formation of a microprojection using etching techniques, which fall into the generic term "micro-machining". Hence the meaning of the term "micro-machining" in the context of the present application and the different techniques or combinations of techniques it may encompass is especially obscure and does not appear limited. It follows that the scope of claim 1 is unclear and not sufficiently defined, contrary to the requirements of Art. 6 PCT.

Consequently a meaningful search cannot be carried out for the claims 1-49 (Art. 17(2)(a) PCT). The search is therefore limited to the claims 50-63 (Art. 17(2)(b) PCT).

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.



(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER see Notification of (Form PCT/ISA/2	of Transmittal of International Search Report 220) as well as, where applicable, item 5 below.
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)
PCT/GB 99/02381	22/07/1999	22/07/1998
Applicant		
THE SECRETARY OF STATE FOR		
This International Search Report has been according to Article 18. A copy is being tra	n prepared by this International Searching Autl ansmitted to the International Bureau.	hority and is transmitted to the applicant
This International Search Report consists X It is also accompanied by	of a total of sheets. a copy of each prior art document cited in this	s report.
1. Basis of the report		and the international application in the
 a. With regard to the language, the language in which it was filed, un 	international search was carried out on the ba less otherwise indicated under this item.	asis of the international application in the
the international search w	vas carried out on the basis of a translation of	
h With regard to any nucleotide ar	id/or amino acid sequence disclosed in the i	international application, the international search
was carried out on the basis of the	e sequence listing : onal application in written form.	
	ernational application in computer readable for	rm.
I ——	o this Authority in written form.	
	o this Authority in computer readble form.	
the statement that the su international application	bsequently furnished written sequence listing as filed has been furnished.	
the statement that the inf furnished	ormation recorded in computer readable form	is identical to the written sequence listing has been
2. X Certain claims were for	und unsearchable (See Box I).	
3. Unity of invention is la	king (see Box II).	
4. With regard to the title,		
	ubmitted by the applicant.	
The text has been estable SILICON MICRO-MACHINE	ished by this Authority to read as follows: D PROJECTION WITH DUCT	
5. With regard to the abstract,		
the text is approved as s the text has been establ within one month from the	ne date of mailing of this international search r	
6. The figure of the drawings to be pu	blished with the abstract is Figure No.	None of the figures
as suggested by the app		None of the figures.
	ailed to suggest a figure.	
X because this figure bette	er characterizes the invention.	



Box I	Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This Inte	ernational Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1.	Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
2. X	Claims Nos.: 1-49 because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically: see FURTHER INFORMATION sheet PCT/ISA/210
3.	Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6,4(a).
Box II	Observations where unity of invention is lacking (Continuation of item 2 of first sheet)
This Int	ernational Searching Authority found multiple inventions in this international application, as follows:
1.	As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.	As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.	As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.	No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remar	The additional search fees were accompanied by the applicant's protest. No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 1-49

The term "micro-machining" has no well established meaning in the art: It describes a generic technology which may use a huge number of different techniques or combinations of techniques. Furthermore it is excessively relative due to the prefix "micro". At the other end it obviously appears that a process for fabricating a -micro-projection must use -micro-fabrication techniques, and consequently -micro-machining of materials.

Additionally it is noted that the document US 5 262 128, acknowledged in the application and mentioned as being unsuitable to fabricate the microprojections in question, discloses in col. 6 the formation of a microprojection using etching techniques, which fall into the generic term "micro-machining". Hence the meaning of the term "micro-machining" in the context of the present application and the different techniques or combinations of techniques it may encompass is especially obscure and does not appear limited. It follows that the scope of claim 1 is unclear and not sufficiently defined, contrary to the requirements of Art. 6 PCT.

Consequently a meaningful search cannot be carried out for the claims 1-49 (Art. 17(2)(a) PCT). The search is therefore limited to the claims 50-63 (Art. 17(2)(b) PCT).

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

International application No.

PCT/GB 99/02381

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

The abstract is changed as follows:

A method of providing a microprojection (180) on the surface of a first material the microprojection having a base portion adjacent the first material and a remote, or a tip portion, and a duct (182) at least in a region of the tip portion and the method comprising micro-machining the first material to provide the micro-projection duct. Various uses of the microprojection are also disclosed including light guides and cuvettes for micro-analytical systems, microneedles for transdermal fluid delivery or the like.

To be accompanied, when published, by Figure 13 of the drawings.





A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 B81B1/00 B81C1/00 G01N21/03

According to international Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC 7 C12M G01N B01L B01J A61M B81B B81C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

ENTS CONSIDERED TO BE RELEVANT	
Citation of document, with indication, where appropriate, of the relevant passages	Relevant to dalm No.
WO 97 04297 A (NORTHEASTERN UNIV) 6 February 1997 (1997-02-06)	50-56,59
page 1, line 31 -page 3, line 35 page 10, line 7 -page 11, line 3 figures 1A,1B,2B,2C	61-63
US 5 137 817 A (BUSTA HEINZ H ET AL) 11 August 1992 (1992-08-11) column 10, line 39 -column 11, line 14; figures 4C,4F,4G	50-57,59
WO 96 37256 A (SILICON MICRODEVICES INC; GODSHALL NED A) 28 November 1996 (1996-11-28) page 5, line 1 -page 6, line 21 claims 1-5; figure 1	50-56, 58,59
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	Citation of document, with indication, where appropriate, of the relevant passages WO 97 04297 A (NORTHEASTERN UNIV) 6 February 1997 (1997-02-06) page 1, line 31 -page 3, line 35 page 10, line 7 -page 11, line 3 figures 1A,1B,2B,2C US 5 137 817 A (BUSTA HEINZ H ET AL) 11 August 1992 (1992-08-11) column 10, line 39 -column 11, line 14; figures 4C,4F,4G WO 96 37256 A (SILICON MICRODEVICES INC; GODSHALL NED A) 28 November 1996 (1996-11-28) page 5, line 1 -page 6, line 21

Further documents are listed in the continuation of box C.	Patent family members are listed in annex.
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family
Date of the actual completion of the international search	Date of mailing of the international search report
9 November 1999	2 3. 12. 99
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentiaan 2	Authorized officer
NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo ni, Fax: (+31–70) 340–3016	Köpf, C



International Application No PCT/GB 99/02381

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Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 262 128 A (LEIGHTON STEPHEN B ET AL) 16 November 1993 (1993-11-16) cited in the application column 2, line 17 - line 52 column 4, line 56 -column 5, line 13 figure 4	50-56, 58,59
X	US 5 383 512 A (JARVIS ERIC E) 24 January 1995 (1995–01–24) column 3, line 42 –column 4, line 60; figure 2	50-56,59
(US 5 457 041 A (GINAVEN ROBERT 0 ET AL) 10 October 1995 (1995-10-10) column 7, line 3 - line 65	50,53,54
A	CAICAI WU ET AL: "Oxyhemoglobin measurement of whole blood specimens in a silicon microfabricated cuvette" MICRO- AND NANOFABRICATED ELECTRO-OPTICAL MECHANICAL SYSTEMS FOR BIOMEDICAL AND ENVIRONMENTAL APPLICATIONS, SAN JOSE, CA, USA, 10-11 FEB. 1997, vol. 2978, pages 155-164, XP000852960 Proceedings of the SPIE - The International Society for Optical Engineering, 1997, USA ISSN: 0277-786X abstract section 2.1. Experimental apparatus	55,60-63

formation on patent family members

Internationa	Application No	
PCT/GB	99/02381	

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WO 9637256	Α	28-11-1996	AU	5869796 A	11-12-1996
US 5262128	A	16-11-1993	AU EP WO	6640190 A 0497885 A 9105519 A	16-05-1991 12-08-1992 02-05-1991
US 5383512	A	24-01-1995	NONE		
US 5457041	Α	10-10-1995	NONE		